COMMONWEALTH OF MASSACHUSETTS

BOARD OF REGISTRATION IN MEDICINE

POLICY 94 - 004

PATIENT CARE ASSESSMENT GUIDELINES FOR

INTRAVENOUS CONSCIOUS SEDATION

MAY 11, 1994

Guidelines

The Board of Registration in Medicine (the Board) is charged by statute with regulating the practice of medicine "in order to promote the public health, safety, and welfare." The Board is also responsible for providing quality assurance programs and technical assistance to licensed health care facilities in the state. Within the scope of the Board's authority is the responsibility to define the safe practice of medicine as well as activities which fall outside such practice. In seeking to provide a better understanding of the expectations it holds for health care facilities and physicians in this state, the Board believes it is useful to issue guidelines which discuss appropriate practice in areas of care in which questions of patient safety have frequently arisen.

Guidelines should be distinguished from rules and regulations: these guidelines are intended to identify a framework for policies concerning Intravenous Conscious Sedation. Generally speaking, when following the guidelines, health care facilities and physicians need provide no further justification for their behavior. Although practice outside the guidelines may be appropriate under some circumstances, such deviations must support therapeutic objectives.

Introduction

A policy on Intravenous Conscious Sedation (IVCS) should be drafted and implemented wherever IVCS takes place. These Patient Care Assessment Guidelines apply to the administration of IVCS to non-pediatric patients (i.e., patients 13 years of age and older) at hospitals and clinics.

The Board recommends that the IVCS policy contain at least five components:

I. Definition
II. Source or Authority for IVCS Policy / Procedures
III. Personnel and Training
IV. Location / Equipment
V. Patient Management and Monitoring.

What follows are suggested elements for inclusion in these components; in certain instances, specific guidelines for patient care are recommended. The Board's suggestions and recommendations are intended to form the basis from which the health care facility's

IVCS policy would be developed and not to supplant standards which may already be in place that conform to the guidelines outlined in this document.

I. Definition

The policy should include a definition of IVCS. The following is an example of one such definition:

> Intravenous Conscious Sedation (IVCS) is a minimally depressed level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously and respond appropriately to physical stimulation and verbal commands. IVCS may be administered during therapeutic, diagnostic or surgical procedures. The drugs, dosages and techniques utilized for IVCS are not intended to produce loss of consciousness. Conscious sedation should be distinguished from two other levels of consciousness: deep sedation and general anesthesia. Deep sedation is a controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused, accompanied by a partial or complete loss of protective reflexes, including the ability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command. General anesthesia is a controlled state of unconsciousness

accompanied by a loss of protective reflexes, including loss of the ability to maintain a patent airway or to respond purposefully to physical stimulation or verbal command.

In actuality, a continuum exists among conscious sedation, deep sedation and general anesthesia. The patient's age and preexisting medical conditions may significantly alter the dosing requirements needed for IVCS. If either deep sedation or general anesthesia is required for the procedure, skilled anesthesia personnel should be available to assist in the management of the patient.

II. Source/Authority for Policy/Procedures on IV Conscious Sedation

The IVCS policy should indicate its source or authority. The Board recommends that authority for these policies originate at the governing body level, i.e., the board of trustees or directors. Ultimately, each department should be responsible for implementing and enforcing the IVCS policy.

Anesthesiologists should not be responsible for the administration of IVCS throughout the facility; however, the Board recommends that the Department of Anesthesia or individual anesthesiologists participate in formulating policies and procedures for patient care during IVCS. In particular, anesthesiologists should

assist in providing expertise and information to other departments or individuals in the following areas:

❑ the appropriate drugs, dosages and techniques for use during IVCS (see Section V);

❑ the development of guidelines for the training, supervision, and credentialing of all individuals involved in the care of patients undergoing IVCS;

❑ patient selection criteria, including the identification of "at risk" patients for whom the delivery of anesthesia by non-anesthesia personnel is inappropriate. The Board strongly suggests that all patients undergoing IVCS be classified according to the American Society of Anesthesiologists (ASA) Physical Status Classification (see Appendix A);

❑ patient monitoring requirements; and

❑ arrangements to ensure the availability of resuscitation support services at all times.

Additionally, anesthesiologists should assist departments in developing mechanisms to continually monitor and evaluate the quality of anesthesia services, including IVCS, wherever these services are delivered. However, monitoring and evaluating the quality of IVCS services are ultimately the responsibility of the department's or facility's quality assurance programs.

III. Personnel and Training

The IVCS policy should specify the personnel and training necessary for safe administration of IVCS. The Board recommends that the minimum number of personnel involved in the care of patients undergoing IVCS during the entire procedure should be two: (1) the physician who performs the diagnostic, therapeutic or surgical procedure; and (2) the individual (M.D., R.N., or P.A.) who monitors the patient and his/her response to both the sedation and the procedure and who is capable of assisting with any supportive or resuscitative measures. One of these two personnel must be available to the patient from the time the procedure has been completed until the time the patient has adequately recovered or has been turned over to personnel performing recovery care. The individual who monitors the patient should have no other significant responsibilities, i.e., no tasks or duties which would compromise his/her ability to monitor the patient. In certain circumstances, e.g., when the patient has been identified as "high risk" or when the procedure to be carried out is particularly complex, a third individual or member of the anesthesia care team should be present to assist with the procedure.

Educational and credentialing mechanisms for IVCS should be part of the usual institutional procedures and should function through any department that has staff undertaking IVCS. These mechanisms should include a process for evaluating and documenting an individual's demonstration of the knowledge, skills and abilities related to the management of patients receiving IVCS. The direct training of staff involved in IVCS should take place either

at the departmental level or at the institutional level with specific departmental input. Courses regarding IVCS, developed with input from anesthesiologists, should be available.

Policies and procedures developed in conjunction with the Department of Anesthesia or individual anesthesiologists should indicate under what circumstances each of the following applies: an anesthesiologist or certified registered nurse anesthetist (C.R.N.A.) must administer IVCS; a non-anesthesiologist physician may administer IVCS; an R.N. may administer the sedation. The Board recommends that if IVCS is administered by non-anesthesia practitioners, a physician trained in airway, life support and medical emergency management should be readily available (i.e., in the same or contiguous building) in case of medical complications and emergencies.

It is the physician with clinical privileges to perform procedures using IVCS who selects and orders the sedation in accord with the IVCS policy. Individuals who administer IVCS should be competent in airway management and resuscitation measures (i.e., at least BLS certified; ACLS certified or equivalent is strongly suggested) and should be educated regarding and demonstrate knowledge in the use, side effects and complications of the medication to be given. The individual responsible for monitoring the patient should have the aforementioned skills and should also have knowledge and experience in the use of oximetry and, when applicable (see Section IV), cardiac monitoring equipment and in the recognition of cardiac arrhythmias.

IV. Location/Equipment

The room where the procedure utilizing IVCS is scheduled to take place should have adequate, uncluttered floor space (to accommodate emergencies) and be equipped with:

❑ a source and means for providing supplemental oxygen (nasal prongs, mask, etc.);

❑ an airway and a self inflating positive-pressure oxygen delivery system capable of delivering 100% oxygen at a 15 liter / minute flow rate for at least 60 minutes. Various bag and mask sizes should be available in those circumstances where appropriate;

❑ a source of suction (portable or wall);

❑ a pulse oximeter with alarm;

❑ a device for taking blood pressure (manual or automatic);

❑ a cardiac monitor with alarm: the Board recommends the use of cardiac monitors for patients with an ASA classification of III or greater or with a history of cardio-pulmonary disease; and

❑ a specific pharmacological reversal agent for the type of sedation to be used.

An emergency cart should be immediately accessible to the room where the procedure is to take place. Means for notifying emergency support services such as respiratory therapy and code pages should be clearly identified and posted in the IVCS location.

V. Patient Management and Monitoring

The IVCS policy should call for the development and use of a standard, time-based (i.e., in real time) form, to be included in the medical record, in which the patient's management and monitoring during IVCS would be documented.

The IVCS policy should contain a list of recommended drugs and dosages, with particular attention given to those drugs which should not be administered by non-anesthesia practitioners. The facility's Pharmacy and Therapeutics Committee (or equivalent) would be an appropriate source for such a list, developed with input from anesthesiologists and specific departments. The Board is not recommending specific drugs and dosages for use during IVCS; however, a suggested list, developed by the Risk Management Committee, Departments of Anesthesia, Harvard Medical School, is attached (Appendix B) for consideration.

The IVCS policy should include the following patient management and monitoring guidelines:

1. Prior to Procedure

It should be ascertained that:

❑ the patient's state of consciousness and medical condition are appropriate for the use of conscious sedation;

❑ preparatory studies appropriate to the procedure and patient have been done;

❑ there is a sedation order given by the physician who will perform the procedure, unless that physician will be administering the medication him / herself;

❑ the patient has no allergy or sensitivity to the prescribed medication;

❑ the patient's pertinent medical history, including current drug regimen, has been obtained / reviewed;

❑ the patient has been NPO for at least six hours prior to the planned procedure, except for clear liquids which may be given up to two hours before the procedure. Medications may be administered with a sip of water. In cases of emergencies, where the patient has not been NPO, IVCS may be dangerous. It should either not be administered or administered judiciously to avoid unconsciousness or suppression of protective airway reflexes.

❑ informed consent has been obtained. The patient / guardian must be informed of the risks and alternatives to IVCS; documentation must be in the medical record prior to procedure;

❑ a physical exam has been conducted which includes assessing / measuring the patient's:

- o estimated weight,
- o vital signs (baseline blood pressure; heart rate; respiratory rate, pattern and quality),
- o baseline oxygen saturation,

- o airway (i.e., an evaluation performed in anticipation of possible intubation, e.g., checking condition of teeth; range of neck motion; ability to open mouth),
- o chest and cardiac status,
- o general neurologic status (e.g., assessing mental status; presence or absence of stroke deficits), and
- o physical status (e.g., ASA physical status category);

❏ the patient has a functioning IV line or heparin lock;

❏ the patient's oxygen requirements are evaluated. The need for administration of supplemental oxygen via nasal prongs should be considered. Patients who are over the age of 60 or who have a medical history significant for heart, lung or kidney disease should be routinely given supplemental oxygen unless specifically contraindicated; and

❏ the patient has been instructed to report any problems associated with the procedure or the IVCS (e.g., pain, difficulty in breathing) to the individual responsible for monitoring the patient.

If any difficulty with the patient or procedure is anticipated, appropriate medical consultation should be obtained.

2. <u>During the Procedure</u>

The individual responsible for monitoring the patient should ascertain and record:

❏ all medication administered (route, site, time, drug, dose);

❏ the amount and means of oxygen administered;

❏ the patient's vital signs (blood pressure, respiratory rate and quality, heart rate, and level of responsiveness) every 5 - 10 minutes. If the patient has been classified ASA III or greater or has a history of cardio-pulmonary disease, the heart rate and rhythm should be displayed continuously by cardiac monitor; and

❏ the patient's oxygen saturation (which is displayed continuously by pulse oximeter) every 5 - 10 minutes.

The patient's head position should be checked frequently to ensure a patent airway. If the patient becomes unstable during the procedure, appropriate medical consultation should be sought immediately.

3. Following the Procedure

The individual whose responsibility it is to monitor the patient should ascertain and record the patient's vital signs (as defined directly above) every 5 - 10 minutes for a minimum of 30 minutes following the last administered dose of IV sedation. Beyond this 30 minute period and, if stable, vital signs should be recorded every 15 minutes until the patient returns to his / her pre-procedure state. Oxygen saturation levels should be obtained if indicated. The patient must be observed for a minimum of 30 minutes following the procedure.

The IVCS policy should include patient discharge criteria for in-patients and ambulatory care patients, as appropriate to the facility. These criteria should include:

❏ patient has stable vital signs and oxygen saturation level;

❏ patient's swallow, cough and gag reflexes are present, or appropriate to baseline;

❏ patient is alert or appropriate to baseline;

❏ patient can sit unaided if appropriate to baseline and procedure;

❏ patient can walk with assistance if appropriate to baseline and procedure;

❏ nausea and dizziness are minimal;

❏ hydration is adequate;

❏ dressing / procedure site have been checked if applicable; and

❏ discharge order has been written by physician. An R.N. may discharge the patient utilizing appropriate criteria based upon a prior discharge order.

If the procedure was done on an outpatient or ambulatory care basis, the patient should be given: (1) written instructions that include an explanation of potential or anticipated limitations on activities, behavior and diet; and (2) a 24-hour emergency contact prior to discharge. Ambulatory care patients should not leave the premises unless they are under the care of a competent adult; they

should be advised to refrain from operating heavy machinery, driving a car, consuming alcohol and making important decisions for 12 to 24 hours.

If the patient is being transferred for further care within the facility, standard criteria for inter-unit transfer should be met.

LIST OF APPENDICES

Appendix A.

American Society of Anesthesiologists

Physical Status Classification

Class I

There is no organic, physiological, biochemical or psychiatric disturbance. The pathologic process for which operation is to be performed is localized and is not a systemic disturbance.

Class II

Mild to moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes.

Class III

Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality.

Class IV

Indicative of the patient with severe systemic disorder already life-threatening, not always correctable by the operative procedure.

Class V

The moribund patient who has little chance of survival but is submitted to operation in desperation.

Appendix B. – Page One

Suggested Drugs and Dosages for Sedation*

This list is not intended to be all inclusive, but should serve as a guide to an upper safe limit for those individuals not having extensive experience with the use of these medications. Some departments may have approved protocols that permit higher or lower doses than noted here. Certain specialists (e.g., anesthesiologists) may routinely exceed these guidelines.

Certain patients may not tolerate even these recommended doses. Furthermore, many of these medications have synergistic respiratory depressant effects; when administered in combination these drugs should be used at lower than those stated below.

Finally, these medications should not be given without familiarity with the rest of the guidelines, and without having the necessary resuscitation equipment and skill at hand.

* Source: "Model Guideline for Sedation by Non-Anesthetists During Diagnostic and Therapeutic Procedures," Risk Management Committee, Departments of Anesthesia, Harvard Medical School, Boston, MA.

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Medication	**Dose**	**Comments**
Sedatives		
Chloral Hydrate	50-100 mg / kg p.o. or p.r.	Up to 1 gram / single dose Max dose = 2 grams
Diazepam	0.1 mg / kg IV slowly (over 3 min.) 0.15-0.3 mg / kg p.o.	
Droperidol	0.02-0.05 mg / kg IV slowly (over 3 min.)	Onset: 3-10 min. Peak: 30 min. Duration: 2-4 hrs.
Midazolam	0.05 mg / kg slowly (over 3 min.) 0.1-0.3 mg / kg IM 0.5-0.7 mg / kg p.o.	
Narcotics (not in infants less than 3 mos.)		
Meperidine	1 mg / kg IM, SQ or IV (slowly)	
Morphine	0.1 mg / kg IM, SQ, or IV (slowly)	
Butorphanol	0.01-0.02 mg / kg IV (slowly)	
Fentanyl	1-3 mcg / kg (0.001-0.003 mg / kg)	Diminished sensitivity to C02 stimulation may persist longer than depression of resp. rate
Antagonists		
Naloxone (for narcotics)	0.01-0.10 mg / kg IV to desired effect	Brief duration of action (30 to 45 min.)
Physostigmine (for anticholinergic syndrome)	0.015-0.025 mg / kg to desired effect	Watch for cholinergic side effects (bradycardia, emesis, cramping, salivation)
Flumazenil (for benzodiazepines)	0.1-0.2 mg (partial antagonism) 0.4-1.0 mg (complete antagonism)	Benzodiazepine withdrawl-induced seizures; residual sedation / hypoventilation
	Pediatric dose not yet established	